

**REMARKS/ARGUMENTS**

The pending Office Action addresses claims 1-15. Applicants appreciate the Examiner's careful review of the claims, and the allowance of claims 8-15. Currently, claims 1-7 stand rejected. By this response, Applicants have amended claims 1, 5 and 6, and canceled claim 4.

Specifically, Applicants have amended claim 1 to recite a system for treating metastases in a load bearing portion of a patient's body comprising a structural support adapted to fit within a cavity in a patient's spine. Support for this amendment can be found in original claim 4, as well as throughout the specification. Accordingly, no new matter is added.

Applicants have amended claim 5 to correct the dependency.

Applicants have amended claim 6 to provide the proper antecedent basis.

**Rejections under 35 U.S.C. § 102(b)**

The Examiner rejects claims 1-3, 6 and 7 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,120,540 of Apple et al. While Applicants disagree with the bases stated by the Examiner, Applicants have obviated this anticipation rejection by including the recitations of claim 4 – which has not been rejected as anticipated – in claim 1.

**Rejections under 35 U.S.C. § 103**

The Examiner rejects claims 4 and 5 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,015,247 of Michelson in view of Apple. As Applicants have amended claim 1 to include the elements formerly recited in claim 4 (which is cancelled herein), Applicants address this rejection with respect to claim 5 and amended claim 1. Specifically, the Examiner states:

Michelson ('247) teaches a system for surgical treatment of diseases of a load bearing portion of a patient's body, comprising:

(structural limitations of the independent claim 1 and dependent claim 4) a structural support implant (50) adapted to fit within a cavity in a patient's spine (vertebrae) (see Figure 5 where the structural support (50) is placed in the cavity of patient's vertebrae, which is depicted as V) and to structurally stabilize the load

bearing portion (see column 5, lines 66-68 and column 6, lines 1-3), the structural support defining an internal space (61);

(Claim 5) wherein a portion of the structural support adapted to be positioned adjacent a patient's spine is formed from a radio-opaque material, preferably Titanium (see column 8, lines 40-43); the radio-opaque material (Examiner states, that Titanium is inherently radio-opaque material, and is capable, or adapted to shield the patient's surrounding tissues of organs from radiation) is adapted to shield the patient's spinal cord from radiation, but he does not teach a radioactive source positionable within the internal space for delivering radiation to tissue surrounding the interstitial space.

However, Apple et al. ('540) an implant system (10) or a structural support adapted to fit an interstitial space in a load bearing portion of a patient's body (hip joint); a radiation source positionable within an internal space for delivering radiation to tissue surrounding the interstitial space (see Figure 6(60) and column 4, lines 21-31).

Without a showing of unexpected results or criticality, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Michelson ('247) by the system of Apple et al. ('540) in order to inhibit heterotopic ossification, as taught by Apple et al. ('540).

The Applicants disagree with the Examiner's rejection.

*The Disclosure of the Apple Reference*

Apple discloses an implant system and method useful for inhibiting heterotopic ossification. The system comprises a prosthetic device that functionally replaces or is additive to a body structure or joint, such as a hip, and a radio source material positioned either on or within the prosthetic device. In order to protect the non-target tissues (e.g., bone) from any radiation dose, and inhibit any heterotopic ossification thereof, first and second shields are formed adjacent to the prosthetic device. [Abstract; Col. 2, lns. 7-10; Col. 3, lns. 34-65.]

*The Disclosure of the Michelson Reference*

Michelson discloses a series of artificial implants, which participate in, and directly cause, bone fusion across an intervertebral space following the excision of a damaged disc. Such devices have a plurality of macro-sized cells and openings that can be loaded with fusion promoting materials, such as autogenous bone, for the purpose of materially influencing the adjacent vertebra to form a bony bond to the implants and to each other. Additionally, the implant casing may be surface textured or otherwise treated by any of a number of known

technologies to achieve a “bone ingrowth surface” to further enhance the stability of the implant and to expedite the fusion. [Col. 6, lns. 6-22.]

*Michelson in View of Apple does not Disclose the Recitations of Applicants’ Claim 1*

Applicants’ claim 1 recites system for treating metastases in a load bearing portion of a patient’s body, comprising a structural support adapted to fit within a cavity in a patient’s spine and to structurally stabilize the load bearing portion, the structural support defining an internal space and a radiation source positionable within the internal space for delivering radiation to tissue surrounding the cavity.

*Because they have Opposite Purposes, There is No Motivation to Combine Michelson with Apple*

Because Michelson is concerned with *promoting bone growth* and Apple is concerned with *inhibiting bone growth*, there is no motivation to combine Michelson and Apple. As noted above, Michelson discloses implants having a plurality of macro-sized cells and openings formed therein. Said openings are for loading with fusion promoting materials, such as autogenous bone, for the purpose of *materially influencing the adjacent vertebra to form a bony bond to the implants and to each other*. [Col. 6, lns. 6-22.] In contrast, the device of Apple seeks to *inhibit heterotopic ossification* by using shields to protect bone from any radiation dose. [Abstract; Col. 3, ln. 63 – Col. 4, ln. 7.] Accordingly, because Apple’s purpose is the exact opposite as that of Michelson, there would be no motivation to combine Michelson and Apple.

*Michelson, Either Alone or in Combination with Apple, does not Teach or Suggest the Recitations of Applicants’ Claim 1*

Further, in no way does Michelson, either alone or in combination with Apple, teach or suggest the recitations of Applicants’ claim 1. As noted above, Michelson teaches artificial implants that directly cause bone fusion across an intervertebral space following the excision of a damaged disc. Nowhere does Michelson teach a structural support *defining an internal space and a radiation source positionable within the internal space for delivering radiation*. Rather, any space found within the Michelson device is loaded with fusion promoting materials, such as autogenous bone. Moreover, nowhere does Michelson disclose a *radiation source*, because *Michelson is not concerned with radiating tissue, but rather promoting bone fusion*.

Apple does not remedy the deficiencies of Michelson. While Apple discloses a device for delivering radioactive energy, Apple does not teach or suggest a system that is adapted to *fit within a cavity in a patient's spine*. Rather, the disclosure of Apple is directed towards *hip and other bone replacement applications*. Further, unlike the spine, the structures of the bones which Apple is directed towards (e.g., the hip, knee, shoulder, foot, hand, limb, jaw, face, and tooth) do not allow for the formation of an *internal space for delivering radiation to tissue surrounding the cavity*. Thus, it would be impracticable for one skilled in the art to combine Michelson with Apple. Accordingly, Applicants' claim 1 is allowable over Michelson in view of Apple. Further, at least because it depends from an allowable base claim, Applicants' claim 5 is also allowable over Michelson in view of Apple.

### Conclusion

In view of the above, each of the presently pending claims (1-3 and 5-15) in this application is in condition for immediate allowance. Accordingly, the Examiner is asked to pass this application to issue.

Dated: January 10, 2005

Respectfully submitted,

By 

Ronald E. Cahill, Reg. No. 38,403

NUTTER MCCLENNEN & FISH LLP

World Trade Center West

155 Seaport Boulevard

Boston, MA 02210-2604

Tel: (617) 439-2000

Fax: (617) 310-9000

Attorneys/Agents for Applicants